PREMARKET NOTIFICATION 510(K) SUMMARY

NOV 2 8 2012

Date Prepared:	July 18, 2012
Submitter:	St. Jude Medical, CRMD
Address:	701 E. Evelyn Avenue Sunnyvale, CA 94086
Phone:	408 522 6832
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Contact Person:	Saket Bhatt
Trade Name/Proprietary Name:	SJM Confirm® Implantable Cardiac Monitor System
Common Name:	Implantable Cardiac Monitor Model Number: DM 2100
Classification:	Class II, 21 CFR 870.2800
Product Code:	MXC
Legally marketed devices to which substantial equivalence is claimed:	SJM Confirm® (Model DM2100) Implantable Cardiac Monitor 510(k) K081365 Medtronic Reveal DX Insertable Cardiac Monitor 510(k) K071655

Device Description:

The SJM Confirm® Implantable Cardiac Monitor (MR Conditional) is a minimally invasive, implantable diagnostic monitoring device with subcutaneous electrodes that are used for sensing and a looping memory for storage of electrograms (EGM). The device is comprised of three main components: the implantable cardiac monitor (Model DM2100), an external patient activator (Model DM2100A) and a programmer. The programmer is used by the physician to communicate to the cardiac monitor and associated programmer software. The programmer is the legally marketed SJM Merlin PCS programmer Model 3650 (with Software Model 3330).

Indications for Use:

The SJM Confirm® Implantable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms that may suggest a cardiac arrhythmia

Technological Characteristics of the Device Compared to the Predicate Device:

The SJM Confirm® ICM (MR Conditional) is identical to the SJM Confirm® ICM Model DM2100 (K081365) in terms of technological characteristics including scientific technology, design, materials, energy source, software, hardware, electrical hardware, shelf life, packaging, sterilization and manufacturing processes. The SJM Confirm® ICM (MR Conditional) with MRI labeling modifications is also substantial equivalent to the Medtronic Reveal DX (K071655). Similar to the SJM Confirm® ICM, Medtronic's Reveal DX is an implantable, single-use programmable device with two surface electrodes to continuously monitor a patient's subcutaneous ECG.

Summary of the Nonclinical Tests Performed:

Verification and validation activities were performed to ensure that the SJM Confirm® ICM devices meet their predetermined design and performance specifications and that the product is substantially equivalent to the predicate device, the SJM Confirm® ICM Model DM2100 (K081365).

In order to ensure MRI compatibility, the following bench testing was performed: Post-MRI Exposure Functional testing after individual field exposure, Device Performance Testing after Exposure to Combined Fields, MRI Induced Force and Torque Testing and RF Field and Gradient Field Induced Heating Tests. Test results demonstrate that the SJM Confirm® ICM is compatible for use in MRI environments.

Since the hardware configuration of the SJM Confirm® ICM (MR Conditional) is identical to its predicate device, the SJM Confirm® ICM Model DM2100 (K081365), the electrical safety and electromagnetic compatibility testing that was performed for the predicate device, also applies to the SJM Confirm® ICM with MRI compatibility. The electrical safety and electromagnetic compatibility test reports were submitted in 510(k) K081365 cleared by FDA on August 15, 2008.

There have been no changes to the components or materials for the SJM Confirm® ICM (MRI Conditional); they are identical to the SJM Confirm® ICM Model DM2100 (K081365). Since there are no new components or materials for the SJM Confirm® ICM (MRI Conditional), no new biocompatibility testing was warranted. Biocompatibility testing of all components and materials was conducted for the SJM Confirm® ICM Model DM2100 (K081365) pursuant to FDA's Guidance Document (#G95-1), Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (1995)".

Conclusion

St. Jude Medical considers the SJM Confirm® Implantable Cardiac Monitor with MRI labeling to be substantially equivalent to legally marketed predicates: SJM Confirm® Implantable Cardiac Monitor System (K081365) and the Medtronic Reveal DX Insertable Cardiac Monitor 510(k) K071655.

The test results and compliance with applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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St Jude Medical, Inc. (CRMD)
c/o: Saket Bhatt
Sr. Regulatory Affairs Specialist
701 E. Evelyn Avenue
Sunnyvale, CA 94086

Re: K122161
Trade Name: SJM confirm implantable cardiac monitor- (MR conditional)
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: II (two)
Product Code: MXC
Dated: November 2, 2012
Received: November 5, 2012

Dear Mr. Saket Bhatt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties.. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SJM Confirm® Implantable Cardiac Monitor (MR Conditional); Model DM2100

Indications For Use:

The SJM Confirm® Implantable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms that may suggest a cardiac arrhythmia

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122161

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